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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,658	04/27/2001	Chester G. Nelson	P-8850.00	9007

27581 7590 07/15/2005

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER
CHANKONG, DOHM

ART UNIT	PAPER NUMBER
2152	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,658	NELSON ET AL.	
	Examiner	Art Unit	
	Dohm Chankong	2152	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1> This action is in response to Applicant's remarks. Claim 5 has been cancelled. Claims 1-4 and 6-25 are presented for further examination.

2> Applicant has sworn behind the primary reference, Snell, US Patent 6.249.705 used in the 102(e) rejection. The rejections using this reference are withdrawn.

3> This action is a non-final rejection.

Response to Arguments

4> Applicant's arguments with respect to claims 1-4 and 6-25 have been considered but are moot in view of the new ground(s) of rejection.

5> In regards the rejection of claim 6 under Snell, U.S Patent No. 5.456.691, Applicant has argued that Snell discloses "software modules...provided to an implantable medical device and not to a medical device interface instrument". However, the functionality of providing the modules to the medical device interface instrument is not present in the claims; the limitations merely recite that the modules have standardized software interfaces to medical device interface instruments. Nothing in claim 6 suggests that the software modules must be "provided" to the medical instruments, merely that the modules are interfaces for the instruments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6› Claims 6 and 9-12 are rejected under 35 U.S.C § 102(b) as being unpatentable over Faisandier, U.S Patent No. 5.800.473.

7› As to claim 6, Faisandier discloses a computerized component architecture for medical device systems, comprising:

a body of software components having standardized software interfaces to medical device interface instruments [Figure 1 | column 4 «line 62» to column 5 «line 2»];

a computerized network of processing equipment with at least two nodes remote from each other [Figure 1 «items 200, 320, 300»];

means for execution of software components via these interfaces from remote processing equipment [column 5 «lines 3-38» | column 6 «lines 33-59»].

8› As to claim 9, Faisandier discloses a software component based IMD administration and control instrument, comprising:

a master processing instrument having network communications capabilities [Figure 1 «item 300»];

an electronics module having telemetry and processing capabilities [Figure 1 «items 320, 310»]; and

at least one component software module resident within the memory of said electronics module [Figure 1].

9› As to claim 10, Faisandier discloses the instrument of claim 9, wherein the master processing instrument comprises an IMD programmer [column 6 «lines 14-18»].

10› As to claim 11, Faisandier discloses the instrument of claim 9, wherein the master processing instrument comprises an IMD extender [column 6 «lines 4-18»].

11› As to claim 12, Faisandier discloses the instrument of claim 9, wherein the master processing instrument comprises an IMD interactive remote monitor [column 4 «line 57» to column 5 «lines 26»].

12› Claim 6 is rejected under 35 U.S.C § 102(b) as being unpatentable over Snell , U.S Patent No. 5.456.691 ["Snell.2"].

13› As to claim 6, Snell.2 discloses a computerized component architecture for medical device systems, comprising:

a body of software components having standardized software interfaces to medical

device interface instruments [Figure 2 «item 34» | column 2 «lines 7-40» where: Snell.2's program modules are analogous to software components];

a computerized network of processing equipment with at least two nodes remote from each other [Figure 1 «items 12, 14, and 16»]; and

means for the execution of software components via these interfaces from remote processing equipment [column 2 «lines 7-40»].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14> Claims 1-4, 7, 8, 13, 15, 17 and 20 are rejected under 35 U.S.C § 103(a) as being unpatentable over Faisandier, in view of Causey, III et al, U.S Patent No. 4.809.697 ["Causey"].

15> As to claim 1, Faisandier discloses a computerized component architecture for medical device systems, comprising:

a body of software components having standardized software interfaces to medical device interface instruments and IMDs [abstract | Figure 1 | column 5 «lines 3-14»]; and

at least one hardware module capable of executing the software components, with the at least one hardware module being deployable [Figure 1 «items 300, 350»];

said hardware module having means for communication with a data communications network [Figure 1 «item 400»], and with a medical device external to the hardware module [Figure 1 «item 200»].

Faisandier does not explicitly disclose that his hardware module (programmer) is deployable to a plurality of medical device interface instruments.

16› In the same field of invention, Causey is directed towards programming of implantable medical devices using an external programmer. Causey discloses a hardware module that is deployable to a plurality of medical device interface instruments [Figure 1 «items 28, 31, 30» | column 5 «lines 41-46» | column 6 «lines 21-25» where : Causey discloses a telemetry head (programmer) that is connected through a cable to the medical interface instrument. This functionality suggests that the telemetry head is deployable to a plurality of different instruments as well]. It would have been obvious to one of ordinary skill in the art to modify Faisandier's programmer into the separate telemetry head and medical interface instrument to allow the system to consist of modules. One would have been motivated to provide such functionality to Faisandier to allow different modules in his system to be easily upgradeable and replaceable [see Causey, column 9 «lines 46-51»].

17› As to claim 2, Faisandier discloses the architecture of claim 1, wherein at least one hardware module has processing and telemetry capabilities [column 1 «lines 30-36»].

18› Faisandier disclose the hardware module installed within an interface instrument [column 10 «lines 10-14» where : the display is the interface instrument] but does not disclose that the module is deployable. However, such a skill is well known and expected in the art. For example, Snell discloses a removable hardware that can be installed or removed from the medical interface instrument [column 6 «lines 3-6»] for the purposes of easily upgrading the interface instrument. Therefore, it would have been obvious to one of ordinary skill in the art to modify Faisandier's hardware module with removable (deployable) functionality. One would have been particularly motivated to provide such functionality for Faisandier to allow the module to be easily installed on different interface instruments [see Snell, column 6 «lines 6-14»].

19› As to claim 4, Faisandier discloses the architecture of claim 1 wherein the component software architecture is optimized to be executed on the hardware module [column 4 «lines 24-35» where : as Faisandier's software is designed to be run on the hardware modules, the software should be optimized for execution on the hardware].

20› As to claim 7, Faisandier discloses the architecture of claim 6, further comprising a hardware module capable of executing the software components [Figure 1 «item 300»] but does not disclose that his hardware module (programmer) is deployable to a plurality of medical device interface instruments.

21› Causey discloses a hardware module that is deployable to a plurality of medical device interface instruments [Figure 1 «items 28, 31, 30» | column 5 «lines 41-46» | column 6 «lines 21-25» where : Causey discloses a telemetry head (programmer) that is connected through a cable to the medical interface instrument. This functionality suggests that the telemetry head is deployable to a plurality of different instruments as well]. It would have been obvious to one of ordinary skill in the art to modify Faisandier's programmer into the separate telemetry head and medical interface instrument to allow the system to consist of modules. One would have been motivated to provide such functionality to Faisandier to allow different modules in his system to be easily upgradeable and replaceable [see Causey, column 9 «lines 46-51»].

22› As to claim 8, Faisandier discloses the architecture of claim 7 wherein said hardware module is integrated within at least one medical device interface instrument [column 10 «lines 10-14» where : the display is the interface instrument].

23› As to claim 13, Faisandier discloses an IMD monitoring and administration network environment implementing reusable and extendable software, comprising:

at least one IMD in communication with at least one IMD interface device [Figure 1];

at least one of said IMD interface device having installed interface software in message-passing relation with at least one network interface [Figure 1 «item 300, 320, 400» | column 4 «lines 10-35»].

Faisandier does not explicitly disclose the network interface is in message passing relation with at least one user node.

24› Faisandier discloses that the user node (display) and the IMD interface device (programmer) are within the same device [Figure 1 «items 300, 320, 350»]. Causey discloses the user node and IMD interface device as separate devices; Causey discloses an IMD interface device with a messaging relation to at least one network interface, said interface in message-passing relation with at least one user node [Figure 1 «items 28, 31, 30» where : Causey's telemetry head is comparable to IMD interface device, item 31 is analogous to the network interface, and item 30 is analogous to the user node]. It would have been obvious to separate the functionality of Faisandier's display and programmer as separate devices as taught by Casey so that the devices can be replaced and updated as necessary [see Causey, column 9 «lines 46-51»].

25› As to claim 15, Faisandier discloses the network of claim 13, wherein the message-passing relation between the interface software installed on said IMD interface and said network interface is capable of transmitting patient cardiac information as curves [column 5 «lines 3-14»] but does not explicitly disclose transmitting analog representations of patient waveform data.

26› Causey discloses transmitting electrocardiogram waveforms (comparable to analog representations) [column 1 «lines 24-30»]. It would have been obvious to one of ordinary skill in the art to modify Faisandier to include the ability to transmit ECG waveforms as taught

by Causey. One would have been particularly motivated to provide such functionality into Faisandier to better monitor patients' health.

27> As to claim 17, Faisandier does not explicitly disclose a live waveform software component and a client live waveform viewer software component.

28> Causey discloses a live waveform software component [column 1 «lines 10-16» : "real-time analysis"],

and a client live waveform viewer software component wherein graphical information is transmitted from the live waveform software component to the client live waveform viewer software component [column 3 «lines 51-56» | column 3 «line 67» to column 4 «line 16»].

It would have been obvious to one of ordinary skill in the art to incorporate Causey's real-time analysis functionality into Faisandier's system to enable the programmer to facilitate comparisons between predicted and measured performance of the implanted medical devices [see Causey, column 3 «lines 54-56»].

29> As to claim 20, Faisandier discloses a method of implementing a compartmentalized, robust IMD monitoring and administration network, comprising the steps of:

establishing a data communications link between at least one IMD and one computer via an interface device [Figure 1];

programming at least one software component to execute on the interface device, the software component being capable of message-passing communications over data communications media [column 6 «lines 1-8»];

programming at least one software component to execute on a linked computer, said software component being capable of operating in a message passing relationship with at least one

30› Claim 14 is rejected under 35 U.S.C § 103(a) as being unpatentable over Faisandier and Causey, in view of Fernandez et al, U.S Patent No. 6.697.103 ["Fernandez"].

31› As to claim 14, Faisandier discloses the IMD monitoring and administration network environment of claim 13, wherein the message-passing relation between the interface software installed on said IMD interface is implemented [column 5 «lines 3-7»], but does not disclose utilizing XML.

32› Fernandez discloses utilizing XML in a controller for communicating with medical devices [column 3 «lines 8-11» | column 4 «lines 35-42»]. It would have been obvious to one of ordinary skill in the art to incorporate XML in Faisandier's message-passing system to enable the devices to communicate over a network allowing remote messaging between the devices.

33› Claims 16 and 19 are rejected under 35 U.S.C § 103(a) as being unpatentable over Faisandier and Causey, in view of Sorge et al, U.S Patent No. 6.565.609 ["Sorge"].

34› As to claim 16, Faisandier discloses the IMD monitoring and administration network environment of claim 15, wherein the analog representations of patient waveform data transmitted via the message passing relation between the interface software installed on said IMD interface and said network interface is implemented by document transmission [column 5 «lines 3-7»], but does not specifically disclose SVG documents.

35› Sorge discloses utilizing SVG for transmitting images compatible with XML [column 6 «lines 39-52»]. It would have been obvious to one of ordinary skill in the art to implement Faisandier's data files as SVG as taught by Sorge. One would have been motivated to perform such an implementation because SVG would allow Faisandier's data (curves) to be scaled to any size or resolution without loss of data.

36› As to claim 19, Snell discloses the IMD monitoring and administration network environment of claim 17, wherein the graphical information is transmitted via a metalanguage [column 6 «lines 60-63»] but does not disclose SVG.

37› Sorge discloses utilizing SVG for transmitting images compatible with XML [column 6 «lines 39-52»]. It would have been obvious to one of ordinary skill in the art to implement Faisandier's patient data files as SVG as taught by Sorge. One would have been motivated to perform such an implementation because SVG would allow Faisandier's patient data to be scaled to any size or resolution without loss of data.

38› Claims 20 and 23-25 are rejected under 35 U.S.C § 103(a) as being unpatentable over Montejo et al, U.S Patent No. 5.161.222 ["Montejo"], in view of Faisandier.

39› As to claim 20, Montejo discloses a method of implementing a compartmentalized, robust monitoring and administration network, comprising the steps of:

programming at least one software component to execute on the interface device, the software component being capable of message-passing communications over data communications media [column 7 «lines 49-64» | column 8 «lines 10-22»];

programming at least one software component to execute on a linked computer, said software component being capable of operating in a message-passing relationship with at least one software component designed to execute on the interface device [column 7 «lines 49-64» | column 8 «lines 10-22» : Montejo's drivers are analogous to software component executed on the linked computer, and the external programs are executed on the interface device. These components communicate through the main module].

Montejo does not explicitly disclose IMDs.

40› Montejo discloses that his invention is directed towards medical devices and medical sensor equipment [column 2 «lines 35-42»]. Faisandier discloses medical sensors that communicate with IMDs [Figure 1]. It would have been obvious to one of ordinary skill in the art to have reasonably inferred that Montejo's medical sensors would be in communications with some sort of medical device, including the IMDs taught by

Faisandier's system. Such an implementation would increase the functionality of Montejo's system allowing it to communicate with a wider variety of medical equipment.

41> As to claim 23, Montejo and Faisandier discloses the method of implementing a compartmentalized, robust IMD monitoring and administration network, wherein the message-passing relationship is effected using client component function calls to public functions of the software component being messaged [see Montejo, Figure 34 «"library functions"» | column 6 «line 49» to column 7 «line 11»].

42> As to claim 24, Montejo and Faisandier discloses the method of implementing a compartmentalized, robust IMD monitoring and administration network, wherein the software component being messaged is implemented in object-oriented programming language [see Montejo, column 7 «lines 49-68»].

43> As to claim 25, Montejo and Faisandier discloses the method of implementing a compartmentalized, robust IMD monitoring and administration network, wherein the software component being messaged is implemented in a manner where it may return a software object in response to the public function call [column 7 «line 65» to column 8 «line 5» | column 9 «lines 47-52»].

44> Claims 21 and 22 are rejected under 35 U.S.C § 103(a) as being unpatentable over Montejo and Faisandier, in further view of Fernandez.

45› As to claim 21, Montejo and Faisandier disclose the method of implementing a compartmentalized, robust IMD monitoring and administration network of claim 20, with a message-passing relationship [column 8 «lines 57-66»] but do not specifically disclose a markup language.

46› Fernandez discloses utilizing XML in a controller for communicating with medical devices [column 3 «lines 8-11» | column 4 «lines 35-42»]. It would have been obvious to one of ordinary skill in the art to incorporate XML in Montejo's message-passing system to enable the devices to communicate over a network allowing remote messaging between the devices.

47›

48› As to claim 22, Montejo and Faisandier disclose the method of implementing a compartmentalized, robust IMD monitoring and administration network of claim 20, with a message-passing relationship [column 8 «lines 57-66»] but do not specifically XML.

49› Fernandez discloses utilizing XML in a controller for communicating with medical devices [column 3 «lines 8-11» | column 4 «lines 35-42»]. It would have been obvious to one of ordinary skill in the art to incorporate XML in Montejo's message-passing system to enable the devices to communicate over a network allowing remote messaging between the devices.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dohm Chankong whose telephone number is (571)272-3942. The examiner can normally be reached on 8:30AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenton Burgess can be reached on (571)272-3949. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DC

Dung C. Dinh
Primary Examiner